Kansas Administrative Regulations

Department of Health and Environment

Article 35.—Radiation

28-35-244a. Radiographic systems other than fluoroscopic, dental intraoral, or computed tomography X-ray systems.

(a) Beam limitation, except for mammographic systems. Each registrant shall ensure that the useful beam is collimated to the area of clinical interest. This requirement shall be deemed to have been met if a positive beam-limiting device meeting the manufacturer's specifications and the requirements of this regulation has been used or if evidence of collimation is shown on at least three sides or three corners of the film, including projections from the shutters of the collimator, cone cutting at the corners, and borders at the film's edge.

(1) General-purpose stationary and mobile X-ray systems including veterinary systems, other than portable systems, installed after the effective date of these regulations.

(A) Each registrant shall use only X-ray systems provided with the means for independent stepless adjustment of at least two dimensions of the X-ray field.

(B) Each registrant shall ensure that a method is provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which the visually defined field appears is perpendicular to the axis of the X-ray beam.

(C) An exemption from paragraphs (a)(1)(A) and (B) may be granted by the secretary for noncertified X-ray systems if the registrant submits a written application for the exemption and that application meets the following conditions:

(i) Demonstrates that it is impractical to comply with paragraphs (a)(1)(A) and (B); and

(ii) demonstrates that the purpose of paragraphs (a)(1)(A) and (B) will be met by other methods.

(2) Additional requirements for stationary general purpose X-ray systems. In addition to the requirements of paragraph (a)(1), each registrant shall ensure that all stationary general-purpose X-ray systems, both certified and noncertified, meet all of the following requirements:

(A) A method shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within two percent of the SID, and to indicate the SID to within two percent.

(B) The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which the device is adjusted.

(C) The indication of the field size dimensions and SID shall be specified in inches or centimeters, or both, and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor that correspond to X-ray field dimensions indicated by the beam-limiting device to within two percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(3) X-ray systems designed for one size of image receptor. Radiographic equipment designed for only one size of image receptor at a fixed SID shall be provided with the means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor and to align the center of the X-ray field with the center of the image receptor to within two percent of the SID, or shall be provided with the means to both adjust the size of and align the X-ray field so that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(4) X-ray systems other than those described in this subsection and veterinary systems installed before the effective date of this regulation and all portable veterinary X-ray systems.

(A) A means shall be provided to limit the X-ray field in the plane of the image receptor so that the field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

(B) A means shall be provided to align the center of the X-ray field with the center of the image receptor to within two percent of the SID, or the means shall be provided to both adjust the size of and align the X-ray field so that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the X-ray beam perpendicular to the plane of the image receptor.

(C) The requirements of paragraphs (a)(4)(A) and (B) may be met with a system that meets the requirements for a general-purpose X-ray system as specified in paragraph (a)(1) or, when alignment means are also provided, may be met with either of the following:

(i) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirements for each combination of image receptor size and SID for which the system is designed, with each such device having clear and permanent markings to indicate the image receptor size and SID for which the system is designed; or

(ii) a beam-limiting device having multiple fixed apertures sufficient to meet the requirements for each combination of image receptor size and SID for which the system is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(b) Radiation exposure control.

(1) Exposure initiation. A means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, including the depression of a switch. Radiation exposure shall not be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(2) Exposure indication. A means shall be provided for visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(3) Exposure termination. A means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a present number of pulses, or a preset radiation exposure to the image receptor. Except for dental panoramic systems,

termination of each exposure shall cause the automatic resetting of the timer to its initial setting or to "zero."

(A) Manual exposure control. An X-ray control shall be incorporated into each X-ray system so that each exposure can be terminated by the operator at any time, except for either of the following:

(i) During any exposure of one-half second or less; or

(ii) during serial radiography, when a means shall be provided to permit the completion of any single exposure of the series in process.

(B) Automatic exposure controls. When an automatic exposure control is provided, all of the following requirements shall be met:

(i) The mode of operation selected shall be indicated on the control panel.

(ii) If the X-ray tube potential is equal to or greater than 50kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses.

(iii) The minimum exposure time for all equipment other than that specified in paragraph (b)(2)(B) shall be equal to or less than one-sixtieth of a second or the time interval required to deliver 5 mAs, whichever is greater.

(iv) Either the product of the peak X-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of the X-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure. However, when the X-ray tube potential is less than 50 kVp, the product of the X-ray tube current and exposure time shall be limited to not more than 2,000 mAs per exposure.

(v) A visible signal shall indicate when an exposure has been terminated at the limits required by paragraph (b)(2)(D), and manual resetting shall be required before further automatically timed exposures can be made.

(4) Exposure duration or timer linearity. For systems that provide for the independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of C $kg^{-1}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This calculation is written as follows:

$$(X_{-1} - X_2) \leq 0.1\,(X_{-1} + X_2)$$

where X_{-1} and X_2 are the average C $kg^{-1}s^{-1}$ (mR/s) values.

(5) Exposure control location. The X-ray exposure control shall be placed so that the operator can view the patient while making any exposure.

(6) Operator protection, except for veterinary systems.

(A) Stationary systems. Each stationary X-ray system shall be required to have the X-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

(B) Mobile and portable systems. Each mobile and each portable X-ray system shall meet the following requirements:

(i) If used for one week or more at the same location, including a room or a suite, meet the requirements of paragraph (b)(6)(A); or

(ii) if used for less than one week at the same location, be provided with either a protective barrier that is at least two meters or 6.5 feet high for operator protection during exposures or a means to allow the operator to be at least 2.7 meters or 9 feet from the tube housing assembly during the exposure.

(7) Operator protection for veterinary systems. All stationary, mobile, or portable X-ray systems used for veterinary work shall be provided with either a protective barrier that is at least two meters or 6.5 feet high for operator protection during exposures or a means to allow the operator to be at least 2.7 meters or nine feet from the tube housing assembly during exposures.

(c) Source-to-skin distance. Each mobile or portable radiographic system shall be provided with the means to limit the source-to-skin distance to equal to or greater than 30 centimeters, except for veterinary systems or systems specifically approved by the FDA.

(d) Exposure reproducibility. When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement shall apply to all clinically used techniques.

(e) Radiation from capacitor energy storage equipment in standby status. The radiation emitted from the X-ray tube when the system is fully charged and the exposure switch or timer is not activated shall not exceed a rate of 0.5 μC/kg (2 milliroentgens) per hour at five centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

(f) Accuracy. Deviation of the measured technique factors from the indicated values of kVp and exposure time shall not exceed the limits specified for each system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for exposure time.

(g) mA and mAs linearity. The following requirements shall apply when the equipment is operated with a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of 40 percent to 100 percent of the maximum rated mA or mAs.

(1) Equipment that provides for the independent selection of X-ray tube current (mA). The average ratios (X_{-1}) of exposure to the indicated milliampere-seconds product C kg^{-1} mAs^{-1} (or mR/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. This calculation is written as follows:

$$(X_{-1}X_2) \leq 0.10(X_{-1} + X_2)$$

where X_{-1} and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of two when the tube current selection is continuous.

(2) Equipment that has a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_{-1}) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum. This calculation is written as follows:

$$(X_{-1}X_2) \leq 0.10(X_{-1} + X_2)$$

where X_{-1} and X_2 are the average values obtained at each of two mAs selector settings, or at two settings differing by no more than a factor of two when the mAs selector provides continuous selection.

(3) Measuring compliance. Determination of compliance shall be based on 10 exposures taken within one hour, at each of the two settings specified by this subsection. These two settings may include any two focal spot sizes, unless one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size shall mean the nominal focal spot size specified by the X-ray tube manufacturer.

(h) Additional requirements applicable to certified systems only. Diagnostic X-ray systems incorporating one or more certified components shall be required to meet the following additional requirements that relate to that certified component or components.

(1) Beam limitation for stationary and mobile general-purpose X-ray systems.

(A) A means of stepless adjustment of the size of the X-ray field shall be provided. The minimum field size at an SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters.

(B) If a light localizer is used to define the X-ray field, the localizer shall provide an average illumination of not less than 160 lux or 15 foot-candles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based on measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980 shall be exempt from this requirement.

(C) The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, when corrected for ambient lighting, of not less than four for beam-limiting devices designed for use on stationary equipment and a contrast ratio of not less than three for beam-limiting devices designed for use on mobile equipment. The contrast ratio shall be defined as I_1/I_2 where I_1 is the illumination at three millimeters from the edge of the light field toward the center of the field, and I_2 is the illumination at three millimeters from the edge of the light field away from the center of the field. Compliance shall be determined by using a measuring instrument that has an aperture of one millimeter in diameter.

(2) Beam limitation and alignment on stationary general-purpose X-ray systems equipped with positive beam limitation (PBL). If PBL is being used, all of the following requirements shall be met:

(A) The PBL shall prevent the production of X-rays when either of the following occurs:

(i) The length or width of the X-ray field in the plane of the image receptor differs, except as permitted by paragraph (h)(2)(C), from the corresponding image receptor dimensions by more than three percent of the SID.

(ii) The sum of the length and width differences as stated in paragraph (h)(2)(A)(i), without regard to sign, exceeds four percent of the SID.

(B) Compliance with paragraph (h)(2)(A) shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than five seconds after insertion of the image receptor.

(C) The PBL system shall be capable of operation, at the discretion of the operator, so that the size of the field can be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters.

(D) The PBL system shall be designed so that if a change in image receptor does not cause an automatic return to PBL function as described in paragraph (h)(2)(A), then any change of image receptor size or SID shall cause the automatic return to PBL function.

(3) Beam limitation for portable X-ray systems. Beam limitation for each portable X-ray system shall meet the beam limitation requirements in paragraph (a)(1) or (h)(2).

(i) Tube stands for portable X-ray systems. A tube stand or other mechanical support shall be used for portable X-ray systems, so that the X-ray tube housing assembly does not need to be handheld during exposures.

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